K130487

PYNG MEDICAL

510(k) Summary

(per 21 CFR 807.92)

JUN 2 5 2013

I. Applicant

Pyng Medical Corp.
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Date Prepared: June 24, 2013

II. Device Name

Trade Name:	***FASTResponder™ Sternal Intraosseous Device***
Device Type:	Intraosseous Infusion Device
Classification Name:	Hypodermic Single Lumen Needle
Regulation Number:	880.5570
Product Code:	FMI
Class:	Class II
Advisory Committee:	General Hospital

III. Predicate Devices

FASTRESPONDER™ STERNAL INTRAOSSEOUS DEVICE is substantially equivalent to the ***FASTx™*** Sternal Intraosseous Device cleared under K100124 and ***FAST1®*** Intraosseous Infusion System cleared under K080865.

IV. Indications for Use of the Device

Indications for Use:

FASTRESPONDER™ Sternal Intraosseous Device is indicated for use in establishing a sternal intraosseous access route in adult and adolescent patients (12 years of age and older) requiring vascular administration of drugs or fluids to facilitate emergency resuscitation.

V. Description of the Device

FASTRESPONDER™ Sternal Intraosseous Device has been designed to provide an alternative to intravenous infusion access of the circulatory system. It utilizes intraosseous infusion in order to facilitate emergency resuscitation through the use of fluids and drugs. The device has been designed for use on the manubrium, the upper (superior) portion of the sternum. The ***FASTRESPONDER™ Sternal Intraosseous Device*** consists

of an introducer handle with target foot which allows the user to target the recommended insertion site and place the infusion tube bone portal into the manubrium.

On withdrawing the introducer handle, the infusion tube bone portal is left firmly placed in the manubrium, the infusion tube luer lock can be connected to a source such as an IV line or standard syringe for infusion of emergency drugs or fluids.

The target foot separated from the handle is adhered to the skin over the insertion site providing protection; the infusion tube strain relief hook is clipped to the target foot for strain relief. The protective dome is placed over the target foot insertion site providing additional protection from external forces.

VI. Summary of the Technical Characteristics

FASTRESPONDER™ Sternal Intraosseous Device has the similar technological characteristics as the ***FAST1®*** Intraosseous Infusion System that received FDA 510(k) clearance under K080865 and ***FASTx™*** Sternal Intraosseous Device that received FDA 510(k) clearance under K100124.

Substantial Equivalence Table giving the similarities and differences between FASTResponder™ and the Predicate Devices K080865 and K100124

	Primary Predicate	**Secondary Predicate to support multiple needles**	**Candidate Device**
Company	Pyng Medical Corp.	Pyng Medical Corp.	Pyng Medical Corp.
Product Name	***FASTx***™ *Sternal Intraosseous Device*	***FAST1***® *Intraosseous Infusion System*	***FASTResponder***™ *Sternal Intraosseous Device*
Product Status	Cleared but recalled	Cleared, On market	Pending clearance
510(k) Number	K100124	K080865	K130487
Product Code(s)	FMI	Equivalent to Primary Predicate	Equivalent to Primary Predicate
Regulation #	880.5570	Equivalent to Primary Predicate	Equivalent to Primary Predicate
Class	II	Equivalent to Primary Predicate	Equivalent to Primary Predicate
Intended Use	The ***FASTx***™ ***Sternal Intraosseous Device*** is indicated for use in establishing a sternal intraosseous access route in adult and adolescent patients (12 years of age and older) requiring vascular administration of drugs or fluids to facilitate emergency resuscitation.	Equivalent to Primary Predicate	Equivalent to both the Primary and Secondary Predicates
Intended User	Paramedic/Doctor	Equivalent to Primary Predicate	Equivalent to Primary Predicate
Target Population	Patients 12 years and older	Equivalent to Primary Predicate	Equivalent to Primary Predicate

	Primary Predicate	**Secondary Predicate to support multiple needles**	**Candidate Device**
Company	Pyng Medical Corp.	Pyng Medical Corp.	Pyng Medical Corp.
Product Name	***FASTx***™ *Sternal Intraosseous Device*	***FAST1***® *Intraosseous Infusion System*	***FASTResponder***™ *Sternal Intraosseous Device*
Where Used	Pre-hospital, ambulance, hospital, battlefield	Equivalent to Primary Predicate	Equivalent to Primary Predicate
IO Insertion Location	Manubrium; superior part of the sternum	Equivalent to Primary Predicate	Equivalent to Primary Predicate
Method of Insertion	Manual (user applied force) insertion with automatic release and automatic depth control	Equivalent to Primary Predicate	Equivalent to Primary Predicate
Removal	Grip infusion tubing near the surface of the skin and pull to disengage portal from cortical bone	Equivalent to Primary Predicate	Equivalent to Primary Predicate
Duration of Use	Less than 24 hours. Until an alternative access is achieved	Equivalent to Primary Predicate	Equivalent to Primary Predicate
Number of Uses	Single use	Equivalent to Primary Predicate	Equivalent to Primary Predicate
Sterility	Delivered in sterile package	Equivalent to Primary Predicate	Equivalent to Primary Predicate
Biocompatibility	Meets requirements of ISO10993	Equivalent to Primary Predicate	Equivalent to Primary Predicate
Fluids infused	Emergency IV fluids	Equivalent to Primary Predicate	Equivalent to Primary Predicate
Fluids aspirated	Bone marrow – optional step to check placement of Infusion Tube	Equivalent to Primary Predicate	Equivalent to Primary Predicate
Materials	Molded plastics and stainless steel	Equivalent to Primary Predicate	Equivalent to Primary Predicate

	Primary Predicate	**Secondary Predicate to support multiple needles**	**Candidate Device**
Company	Pyng Medical Corp.	Pyng Medical Corp.	Pyng Medical Corp.
Product Name	***FASTx***™ *Sternal Intraosseous Device*	***FAST1***® *Intraosseous Infusion System*	***FASTResponder***™ *Sternal Intraosseous Device*
Contraindications	None known	Equivalent to Primary Predicate	Equivalent to Primary Predicate

	Primary Predicate	**Secondary Predicate to support multiple needles**	**Candidate Device**
Company	Pyng Medical Corp.	Pyng Medical Corp.	Pyng Medical Corp.
Product Name	***FASTx™*** *Sternal Intraosseous Device*	***FAST1®*** *Intraosseous Infusion System*	***FASTResponder™*** *Sternal Intraosseous Device*
Cautions/Warnings	**PRECAUTIONS:** • The ***FASTx ™ Sternal*** is designed to penetrate 6mm into the manubrium. Qualified professionals should determine any appropriate or necessary exceptions, either inclusions or exclusions, to the criterion "for patients 12 years and older". • Proximal tip of Infusion Tube contains metal. ***The function of the device may be affected by:*** • Compromised skin over the insertion site such as trauma, infection or burns • Fracture of the sternum or vascular injury which may compromise the integrity of the manubrium or its vascularization • Midline sternotomy scars	• The ***FAST1™*** Intraosseous Infusion System is designed to penetrate 6 mm into the manubrium. • Adult and adolescent* patients are expected to have a manubrium thickness greater than 6 mm. Qualified professionals should determine any appropriate or necessary exceptions, either inclusions or exclusions, to the criterion "For use with adult and adolescent* patients" * (12 years of age and over). • Severe skin compromise such as trauma, infection or burns over the infusion site may interfere with use of the device. • Check for fracture of the sternum or vascular injury which may compromise the integrity of the manubrium or its vascularization.	Equivalent to Primary Predicate

	Primary Predicate	**Secondary Predicate to support multiple needles**	**Candidate Device**
Company	Pyng Medical Corp.	Pyng Medical Corp.	Pyng Medical Corp.
Product Name	***FASTx***™ *Sternal Intraosseous Device*	***FAST1***® *Intraosseous Infusion System*	***FASTResponder***™ *Sternal Intraosseous Device*
Cautions/Warnings (continued)	**WARNINGS:** • Safety in patients with very severe osteoporosis has not been proven • Insertion in sites other than the manubrium may result in ineffective infusion and/or serious injury to the patient.	• Check for midline sternotomy scars - the device may be less effective in patients with a previous midline sternotomy. • Safety of the ***FAST1***™ in patients with very severe osteoporosis has not been proven. • Insertion of the ***FAST1***™ in sites other than the manubrium may result in ineffective infusion and may result in over-penetration of the infusion tube with consequent serious injury to the patient.	Equivalent to Primary Predicate

VII. Safety & Effectiveness

FASTRESPONDER™ Sternal Intraosseous Device has the same intended use and similar technological characteristics as the predicate devices. The differences in technological characteristics between the new device and the predicate devices do not raise issues of safety and effectiveness of the ***FASTRESPONDER™ Sternal Intraosseous Device.***

- Bench tests, functional testing, and validation studies were conducted.
- The infusion needle tubing and portal tip of the ***FASTRESPONDER™ Sternal Intraosseous Device*** are comparable to the predicate device.
- The risk analysis was conducted according to ISO 14971:2012.
- Applicable biocompatibility testing was in accordance to the requirements of ISO 10993-1.
- The sterilization validation study was conducted in accordance to ISO 11137 "Sterilization of health care products – Radiation- Part2: Establishing the sterilization dose".
- Pyrogen study was conducted in accordance to USP: "Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices".
- Packaging validation was completed in accordance with ISO 11607.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 25, 2013

Pyng Medical Corporation
Ms. Michele Tyler
Quality Assurance and Regulatory Affairs Vice President
13480 Crestwood Place Unit 210
Richmond BC Canada V6V 2J9

Re: K130487
Trade/Device Name: FASTResponder™ Sternal Intraosseous Device
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: March 29, 2013
Received: April 1, 2013

Dear Ms. Tyler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner DDS, MA Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4. Indication for Use Statement

510(k) Number (if known): K130487

Device Name: *FASTResponder™ Sternal Intraosseous Device*

Indications for Use:

FASTResponder™ Sternal Intraosseous Device is indicated for use in establishing a sternal intraosseous access route in adult and adolescent patients (12 years of age and older) requiring vascular administration of drugs or fluids to facilitate emergency resuscitation.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Rick Chapman Date: 2013.06.24 16:47:23 -04'00'

Division Sign-Off)
ivision of Anesthesiology, General Hospital
ıfection Control, Dental Devices

510(k) Number: K130487